

Quick Start Guide

encevis 2.0



Manufacturer:

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Giefinggasse 4; 1210 Vienna; Austria
Date of manufacture: 2021



Use-by date:

Windows 10: 10/2025



Notified Body:

mdc medical device certification GmbH;
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Caution: Please read paragraphs marked with this symbol carefully
as they contain important safety information.



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Warnings and precautions



This version of encevis is CE-certified as a medical device. If your country requires any other approval for medical devices you must not use this version of encevis. If you are located in a country that requires FDA approval for medical devices, please contact your local distributor to receive an FDA approved version of encevis. For all other countries please contact your local distributor to receive a version of encevis that is not certified as a medical device and can be used outside countries that accept the CE or FDA mark.



The modules from encevis for the automatic analysis of EEG cannot replace the examination by the physician. As for any other automatic procedure there can be inaccuracies during the analysis with encevis. The original EEG still needs to be used for the evaluation and the results of encevis need to be confirmed based on the unaltered raw EEG trace.



encevis does not provide any diagnosis or diagnostic recommendation, conclusion or prediction of the patient's state. It remains the responsibility of the physician to decide on the diagnosis or to induce treatment.



The use of the software cannot replace the real-time surveillance by medical staff particularly of the vital functions. The patient's safety remains the responsibility of the medical professional.

The EEG-data should be recorded at least with the complete 10/20 set of scalp electrodes. For aEEG and background frequency the EEG must be available from at least three scalp electrodes.

The maximum length for on continuous EEG recording with a 10/20 set of scalp electrodes that can be reviewed and analyzed is 10 days. If a recording is longer than 10 days encevis will stop processing.

encevis artifact reduction does not remove all interference and reduces only interference coming from EMG, electrode artifacts or optionally eye artifacts. It can change areas of the EEG that show cerebral activity. encevis artifact reduction works only with electrodes defined in the 10/10 system and additional T1-, T2-, SP1-, and SP2- electrodes.

encevis seizure detection cannot be used as an alarm system, since there may be a delay of several minutes between the clinical onset of a seizure and the display of the detected pattern. Some EEG-events with epileptic seizures that have an electrographic correlate might be missed. For this reason, encevis can only support but cannot replace the qualified expert in the real-time monitoring.

Some EEG-events where spikes occur might not be detected with encevis Spike Detection. The detection of such events with the encevis spike detection cannot replace the analysis by a qualified expert.



encevis detection of rhythmic and periodic pattern, burst suppression, aEEG or any other module included in encevis should not be used as an alarm system, since the visualization of patterns could be delayed by up to several minutes.

Some events, where patterns defined in the Standardized Critical Care EEG Terminology of the American Clinical Neurophysiology Society including Burst Suppression Detection are visible in the EEG, might be missed. It can happen that the localization of patterns is not correct. All measures of encevis must be evaluated in combination with the original raw EEG and must not be the only basis for a diagnosis, treatment or change of treatment.



The heart rate trace shown in encevis can never replace an ECG monitor. The trace shown in encevis is only intended to provide additional information that can help in the interpretation of the EEG. It must never be used to monitor the heart function of the patient. It must always be verified based on the original raw ECG trace.

encevis source localization may only be used with electrodes defined in the 10/10 electrode system configuration. The use of electrodes other than those included in the 10/10 system may lead to an error message. The results of a source localization are never unambiguous and may differ from the actual position of the source of the EEG activity. The use of a standard head model can lead to deviations in the localization of the EEG activity. The results of encevis source localization can only support the location based on the analysis of the original EEG by a qualified expert, but not replace it.

Contraindications

There are no known contraindications for the use of encevis.

Possible adverse effects

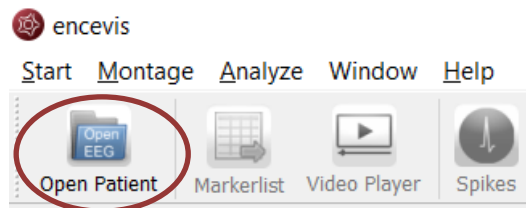
There are no known possible adverse effects when using encevis.

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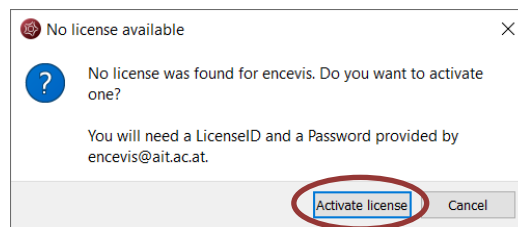
Installation and license activation

Once you have downloaded **encevis**, continue with the following steps:

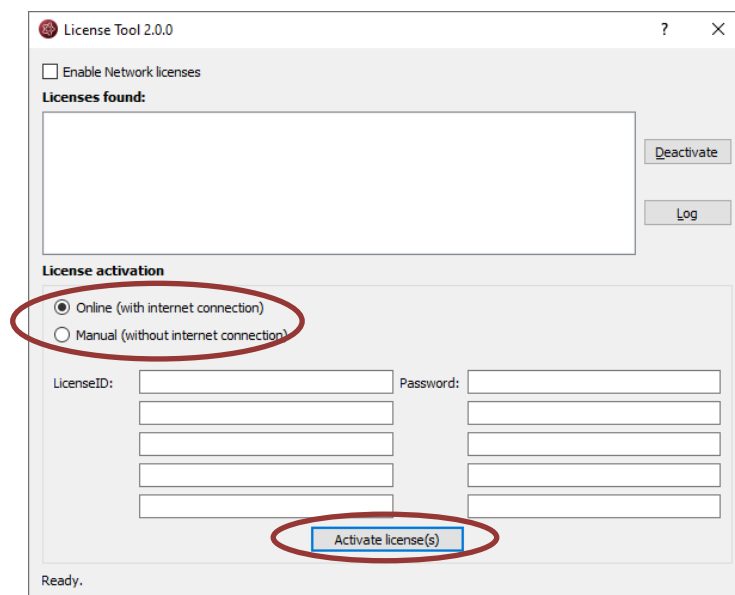
1. Start the **encevis** installer, this will guide you through the installation process.
2. Start **encevis**. You will find the following toolbar:



3. Press the button “**Open Patient**”, the following window will pop up:

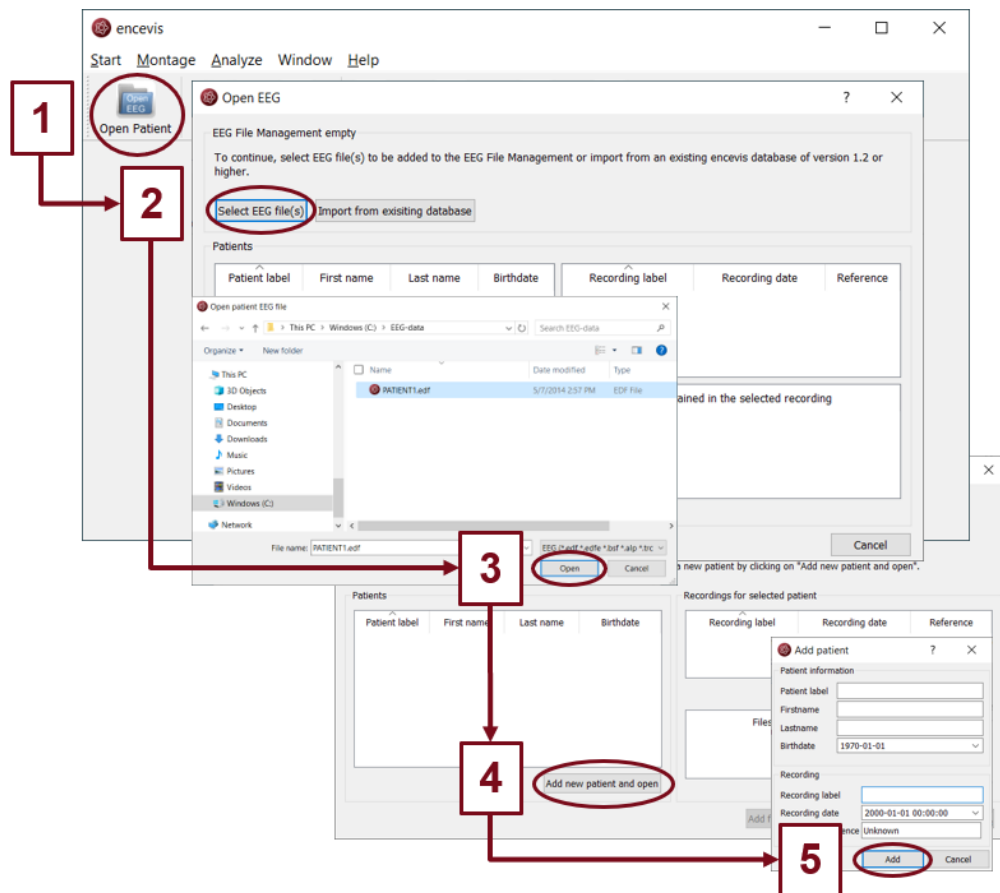


4. Press “**Activate license**”, the License Tool will pop up:



5. If you are connected to the internet, select „**Online**“ as activation mode. Otherwise, select “**Manual**” and contact your distributor in order to get the keys for the manual activation. Then enter LicenseIDs and passwords and press “**Activate license(s)**“. You may need to **restart encevis** before you continue

Open EEG file(s) in 5 steps

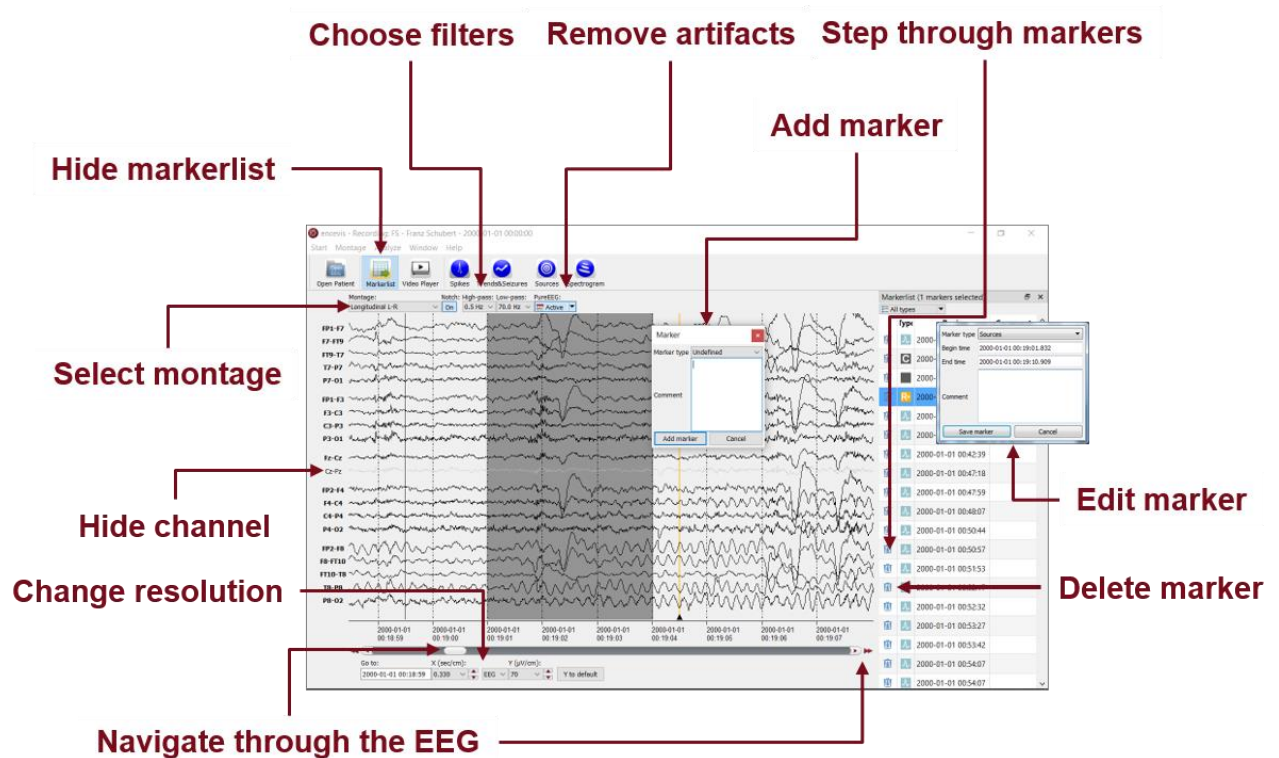


1. Press **"Open Patient"** or select the menu point **Start > Open Patient**.
2. Press **"Select EEG file(s)"**
3. Select the EEG file(s) that you would like to open.
4. If the file(s) are already registered in the EEG file management they will be opened immediately, otherwise a window will pop up. There, Press **"Add new patient and open"**, a new window will pop up.
5. Fill in the fields of the "Patient information". Fill in the recording label and the recording date and the reference used for the EEG recording. Press **"Add"**.



More information can be found under the menu point **Help > encevis Help**.

Review EEG



You have now the possibility to use all functionalities of encevis:

- Navigate easily through the EEG.
- Remove artifacts with PureEEG.
- Change the settings of the channels by selecting a montage and hide channels.
- Change the resolution in time and in voltage.
- Select notch, high-pass and low-pass filters.
- Watch the EEG in two windows at the same time.
- Create, review and change markers for special EEG events.
- Markers are saved with the data in the marker list and can be reviewed anytime.
- Start automatic EEG analysis.
- View video stored with the EEG if available.

Notice

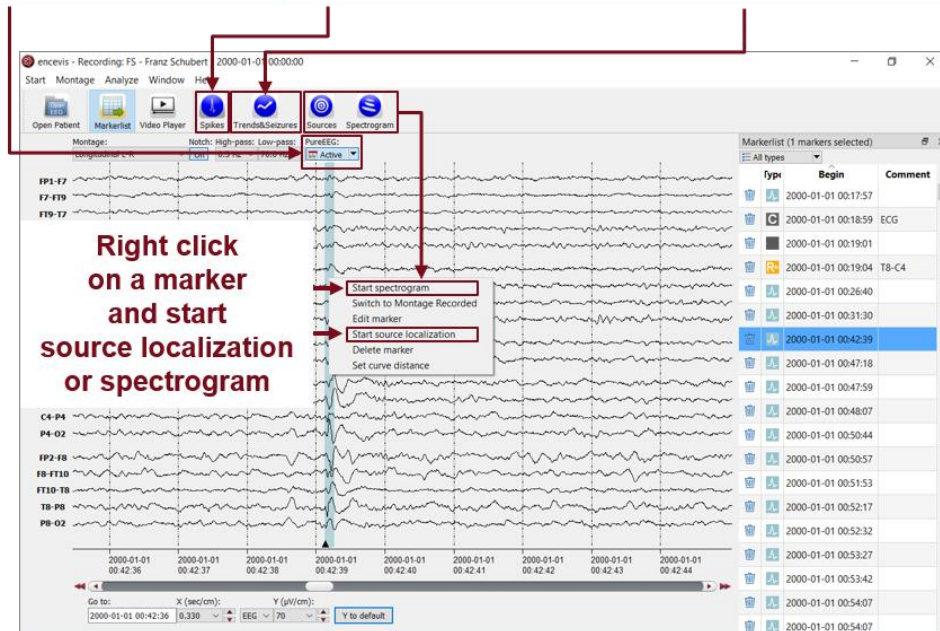
To play videos stored with the EEG you need to have the proper video codecs installed. A great selection of free available codecs for play various video formats is available at https://codecguide.com/download_kl.htm.



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Start automatic EEG analysis

Start artifact reduction Start spike detection Start trends and seizure detection



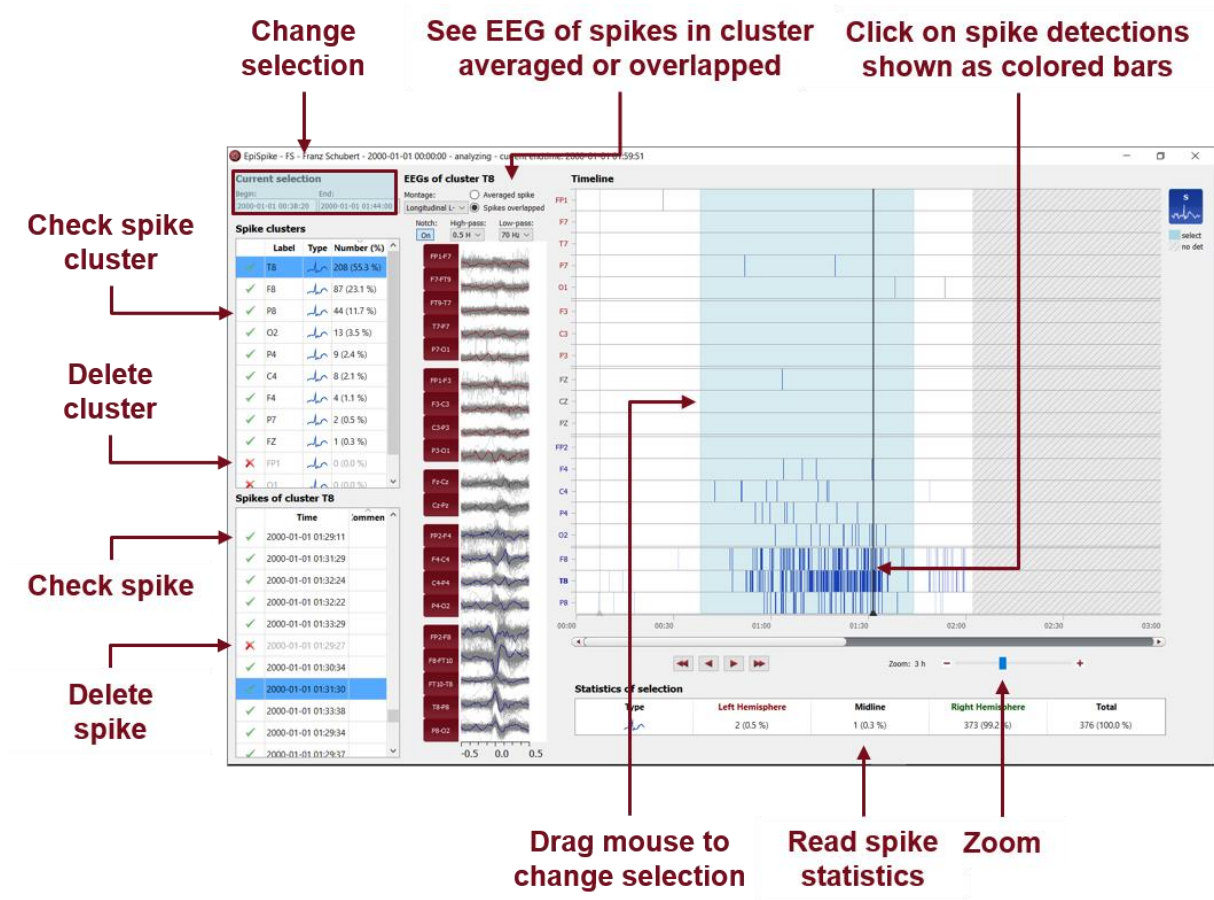
encevis offers you a series of automatic EEG analysis tools:

- **Spikes:** the automatic spike detection detects spikes, clusters them by localization and visualizes the results for easy review in the EpiSpike window.
- **Trends&Seizures:** the advanced EEG trending calculates automatic detection of seizures, of rhythmic patterns, qEEG, aEEG, the heart rate and visualizes the results in the NeuroTrend window.
- **Seizure detection:** the detected seizures are shown in the marker list and have four different types: rhythmic, rhythmic+, tonic and tachycardia.
- **Sources:** you can easily start the source localization by right-clicking on a marker in the EEG traces. The results are shown in the EpiSource window.
- **Spectrogram:** you can easily start a time-frequency analysis by right-clicking on a marker in the EEG traces.



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Spike detection - EpiSpike



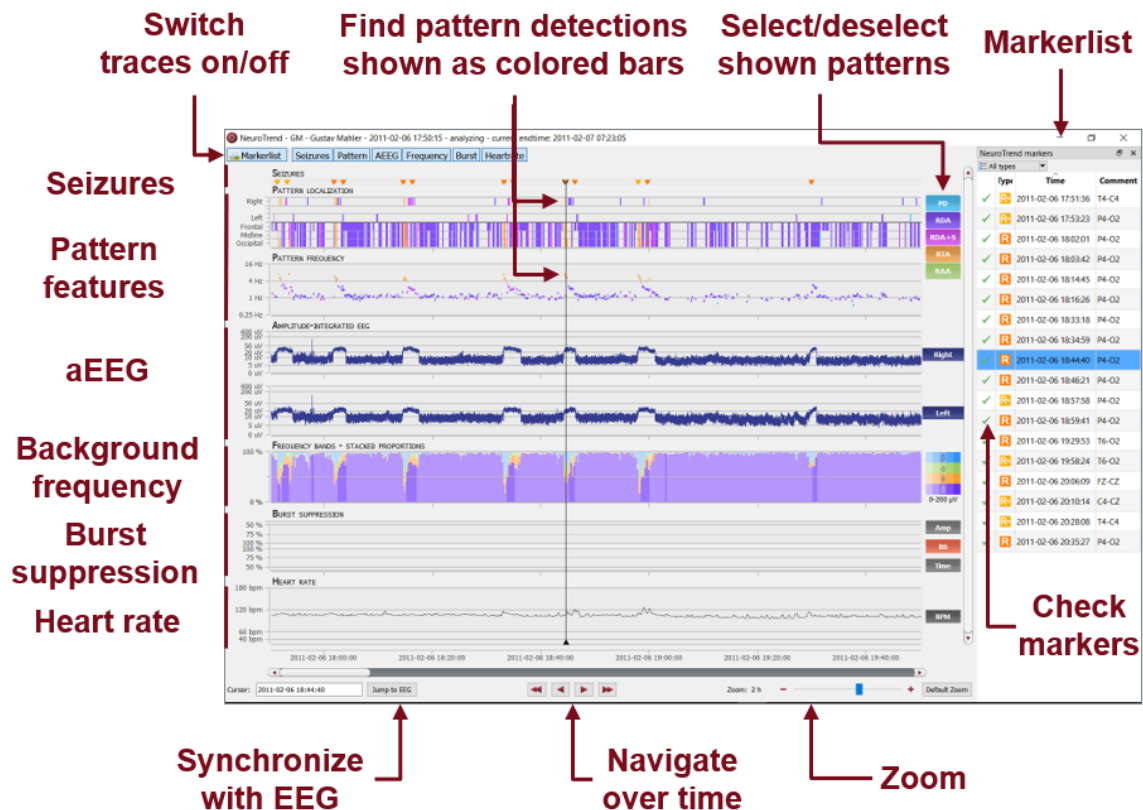
Start the spike detection EpiSpike and use all its functionalities:

- Start the detection on the complete time range or specify a time segment you are particularly interested in.
- Find the spike detections on a timeline as blue bars clustered and arranged by their localization.
- Zoom in and zoom out of the timeline using the mouse wheel.
- Click on a detection to see its EEG and find it in the spike list.
- Choose if you want to see the average spike EEG of the cluster or all spikes overlapped.
- Go through the lists of spike clusters and their spikes and remove detections you do not want.
- Change time of selection for review and statistics.
- Synchronize with the EEG in the EEG viewer.



More information can be found under the menu point **Help > encevis Help**.

Trends and Seizures - NeuroTrend



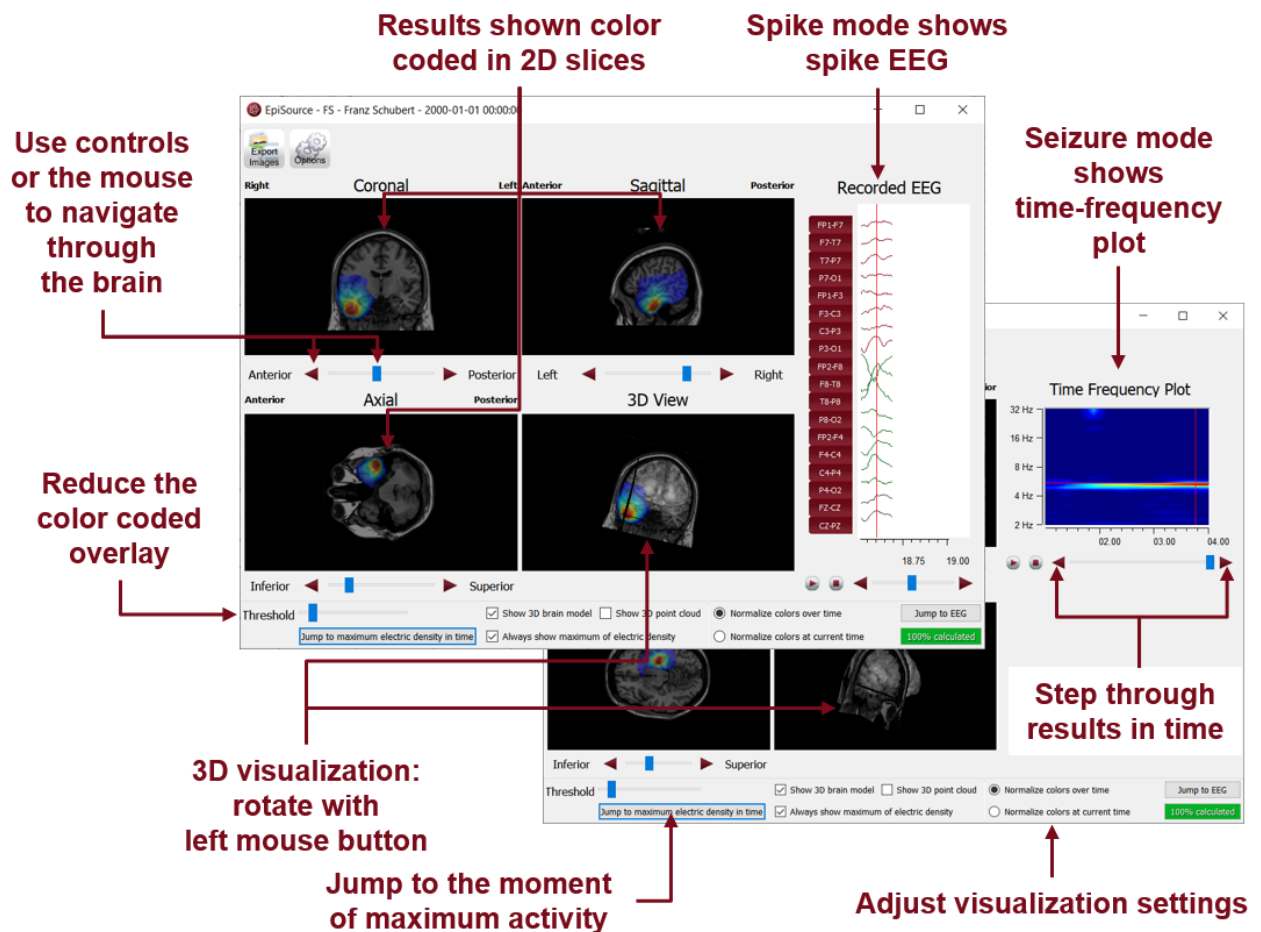
Start the trends and seizure detection NeuroTrend and use all its functionalities:

- Find color-coded detection of different types of seizures: highSens, rhythmic, rhythmic +, tachycardia and tonic.
- Find the detection of five different patterns: periodic discharges (PD), rhythmic delta activity (RDA), rhythmic delta activity + spikes (RDA+S), rhythmic theta activity (RTA), rhythmic alpha activity (RAA).
- Read localization and frequency of the detected patterns.
- See the amplitude-integrated EEG and the proportion of the frequencies as continuous measures.
- Find burst suppressions and attenuations.
- Read the heart rate based on the ECG.
- Navigate in time and synchronize with the EEG shown in the encevis viewer.
- Zoom in and zoom out using the mouse wheel.
- Select or deselect patterns that you want to have shown or hidden.
- Switch on/off the traces you want to have displayed.



More information can be found under the menu point **Help > encevis Help**.

Source localization - EpiSource



Start the source localization EpiSource and use all its functionalities:

- Choose between seizure mode (seizure markers: 1s-5min) and spike mode (spike markers: 20-500ms).
- See the results of the source localization as color-coded overlay to the structural MRI. High activity is red. Low activity is blue.
- Review the results in the three 2D slices (Coronal, Sagittal and Axial).
- Navigate through the slices using the controls or the mouse.
- Review the results in the 3D visualization.
- Zoom in and zoom out using the mouse on the screen.
- Step through the results in time or just jump to the time point of maximum activity.
- Adjust several visualization settings.
- Export the results as images.



More information can be found under the menu point **Help > encevis Help**.